

Inflator B30 and Inflator B40

A Description

The GENOSS Inflator B30 and GENOSS Inflator B40 are an inflation/deflation Device with an analog pressure gauge that registers pressures from vacuum to 30 and 40 atmospheres (vacuum to 440.88 or 587.84 psi). The GENOSS Inflator is consisted of a thread plunger and locking button which allow for the generation and sustaining of pressure. A Three way stopcock should be included for use during preparation of the device and in conjunction with interventional devices.

Inflator (GBI-B30)	Max. Pressure	30atm (440.88psi)
	Barrel Capacity	20ml (cc)
Inflator (GBI-B40)	Max. Pressure	40atm (587.84psi)
	Barrel Capacity	30ml (cc)
3 way Stopcock	Max. Pressure	40atm (587.84psi)

B Indication

The GENOSS Inflator B30 and GENOSS Inflator B40 are used to inflate and deflate balloon catheters or other interventional devices as well as to monitor pressure within the balloon during the procedure.

C Warning

Use of these devices should be restricted to those specialists and/or physicians trained to perform vascular procedures that utilize interventional devices such as balloon dilation catheter. Always follow the manufacturer's directions accompanying the balloon catheter for instructions for use, maximum inflation pressures, precautions, and warnings for use. Improper tightening of the connection between the Inflator and balloon dilation catheter may result in introduction of air into the vascular system. Do not inject any fluid if air bubbles are visible within fluid path of the inflator. The pressure displayed on the inflator must not exceed maximum recommended balloon catheter inflation pressure. Prolonged exposure to contrast medium may cause components of the device to malfunction and thereby create a safety hazard. Use only radiopaque inflation medium recommended by the dilation catheter manufacturer.

D Precautions

The components of the package have been delivered STERILE. The Inflator B30 and Inflator B40 are for single use only; do not reuse. Thoroughly inspect the components prior to use to verify that no damage has occurred during handling. Do not use if the package and/or its contents have been damaged, or contamination or damage is suspected. If damage is found, call your GENOSS representative. After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy. Do not resterilize, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing. Note the "Use by" date specified on the package. Refer to the appropriate device labeling for indications associated with the use of interventional device. Do not expose the GENOSS Inflator B30 and GENOSS Inflator B40 to organic solvents, e.g., alcohol.

E Direction for use

- 1) Connect the GENOSS Inflator B30 and GENOSS Inflator B40 to a 10 and 20cc syringe filled with contrast medium or mixed contrast medium with normal saline.
- 2) To fill the GENOSS Inflator B30 or GENOSS Inflator B40 with contrast medium:
 - a) Open the stopcock and press the locking button to its UNLOCK position.
 - b) Aspirate contrast medium by slowly withdrawing the plunger.
 - c) Evacuate air in the GENOSS Inflator B30 or GENOSS Inflator B40 by slowly injecting the necessary volume from the GENOSS Inflator B30 or GENOSS Inflator B40 back into the syringe.
 - d) Repeat steps 2) b through 2) c until all the air is removed from the GENOSS Inflator B30 or GENOSS Inflator B40 and about 6-20cc of contrast remains.
- 3) To create a closed system, release the locking button.
- 4) Connect the GENOSS Inflator B30 or GENOSS Inflator B40 to the inflation port of the interventional device such as balloon catheter hub.
- 5) When balloon inflation is desired, rotate the plunger handle clockwise to increase pressure or counterclockwise to decrease pressure.
- 6) Pressure can be quickly released by pressing the locking button to the UNLOCK position and then retracting the plunger handle. To maintain this position, release the locking button to the LOCK position.
- 7) To quickly release from the vacuum position, press the locking button to the UNLOCK position.



















F Contents of Package

Contains one or more of the following: GENOSS Inflator B30 or GENOSS Inflator B40, 3 way stopcock.

G Storage

Store at room temperature (1°C-30°C) in dry and dark places.

H Symbols

	Catalogue number		Batch code
	Do not reuse		Date of manufacture
	Caution		Use by
	Sterilized using ethylene oxide		Manufacturer
	CE Mark		Authorized representative
	Do not resterilize		Keep away from sunlight
	Fragile, handle with care		Do not use if package is damaged
	Consult instructions for use		Temperature limitation
	Keep dry		Quantity per package

MS-P2254/IFU-DS1503(Rev.4,2401)